

**REMARKS**

Claims 1-15 were pending in the application. Applicants note that the Office Action Summary shows claims 1-9 and 12-15 pending and claims 8, 9, 12 and 13 withdrawn from consideration. However, claims 8, 9, 12 and 13 were rejected and were elected in response to the restriction requirement made final in the pending Office Action. Thus, at the time the Office Action issued, claims 1-15 were pending and claims 8, 9, 12 and 13 were subject to examination.

Claims 1-11 and 13-15 have been canceled without prejudice to the subject matter contained therein. Claim 12 has been amended to more clearly define certain embodiments of the invention. Claims 16-25 have been added to claim additional embodiments. Each of the added claims is dependent on claim 12 and, thus, is subject to examination under the restriction requirement. Support for the subject matter of claims 16-25 may be found in the specification at least on page 14, lines 25-26 and page 15, lines 13-20, as well in as the originally filed claims. No new matter was added. Claims 12 and 16-25 are now pending.

Claims 8, 9, 12 and 13 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

According to the Office Action, the specification lacks a reasonable level of guidance for methods for the systemic minimization of the production of TNF- $\alpha$ . This rejection is moot in view of amended claim 12 and the new claims. Applicants have amended the claims in order to expedite prosecution of the application and do not concede the correctness of the Examiner's rejection. Amended claim 12 is now directed to a method for minimizing the production of TNF- $\alpha$  caused by an inflammatory response in a patient comprising administering a locally effective TNF- $\alpha$  lowering amount of bioactive glass particles with a size less than about 20  $\mu\text{m}$  to the patient. Thus, the method now claimed is directed to administering a locally effective amount of bioactive glass particles.

The examples in the specification illustrate the results of intraperitoneal administration of bioactive glass to mice. The results of Example 1 show that the bioactive glass was not directly pro-inflammatory since no TNF- $\alpha$  response was elicited. Example 2

and Figure 5 show that mice that received bioactive glass particles prior to Dgal/LPS had significantly lower plasma TNF- $\alpha$  levels than did controls. The bioactive glass particles were effective locally in the peritoneal cavity. An article published on experiments as disclosed in the examples of the application is attached hereto and reflects further the ability of bioactive glass particles to minimize the production of TNF- $\alpha$  when administered locally. See, *"Bioglass® Attenuates A Proinflammatory Response in Mouse Peritoneal Endotoxiosis"*, Shock, February, 2002.

In view of the teachings of the specification and the examples provided which support the claims, Applicants submit that the claims would enable one of skill in the art to make and/or use the invention. Thus, Applicants respectfully request that the rejection under §112 be withdrawn.

Applicants believe they have responded to all matters raised in the above referenced Office Action and that the application is now in condition for allowance. If the Examiner has any questions concerning this Application or this Response and Amendment, she is invited to contact the undersigned.

Respectfully submitted,  
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

*Mary B. Grant*

By: Mary B. Grant  
Registration No. 32,176

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(919) 941-9240

Date: October 23, 2002